DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 31 2010

Re: Vimpat
NDA 22-254
Patent Nos. 5,654,301 and RE38,551
Docket Nos.: FDA-2009-E-0175
FDA-2009-E-0173

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 5,654,301 and RE38,551, filed by Research Corporation Technologies, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for Vimpat (lacosamide), the human drug product claimed by the patents.

The total length of the regulatory review period for Vimpat (lacosamide) is 3,452 days. Of this time, 3,055 days occurred during the testing phase and 397 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 19, 1999.

   The applicant claims November 14, 2003, as the date an investigational new drug application (IND) became effective. However, according to FDA records, this IND was not the first IND received for this active ingredient. In general, FDA has used the first IND of the active ingredient of the drug product as the beginning of the testing phase, if information derived from this first IND was or could have been relied on or was relevant for approval to market the drug product. FDA records indicate that the effective date of the first IND for lacosamide was May 19, 1999, which was 30 days after FDA receipt of this first IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: September 28, 2007.

   FDA has verified the applicant's claim that the new drug application (NDA 22-254) was submitted on September 28, 2007.

3. The date the application was approved: October 28, 2008.

FDA has verified the applicant's claim that NDA 22-254 was approved on October 28, 2008.

Please note: we have determined that the regulatory review period for the human drug product, Vimpat, approved under NDA 22-254 for Vimpat Injection, is the same as the regulatory review period determined for NDA 22-253 for Vimpat Tablets.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Kevin G. Shaw
Hogan & Hartson, LLP
555 Thirteenth Street, NW
Washington, DC 20004